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Paper 75
31 March 2009

UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

Patent Interference No. 105,613 (RT)

AMGEN, INC.
(09/895,943),
Junior party,

v.

HUMAN GENOME SCIENCES, INC.
and Schering Corp.
(6,844,170),
Senior party.

Before: RICHARD TORCZON, SALLY GARDNER LANE, and MICHAEL P. TIERNEY, *Administrative Patent Judges*.

TORCZON, *Administrative Patent Judge*.

JUDGMENT
Bd.R. 127
On merits

I. INTRODUCTION

In an accompanying decision (Paper 74), the Board holds that the senior party (HGS) did not satisfy the utility requirement in its disclosure. Since utility is also a requirement for reduction to practice, *University of*

Rochester v. G.D. Searle & Co., 358 F.3d 916, 926 (Fed. Cir. 2004), HGS no longer has a constructive reduction to practice. Consequently, it is appropriate to enter judgment.

II. JUDGMENT

ORDERED that judgment be entered against HGS for count 1, the sole count (Paper 1);

FURTHER ORDERED that claims 1-34 of the HGS involved patent (Paper 4) be CANCELED, 35 U.S.C. 135(a); and

FURTHER ORDERED that a copy of this judgment be entered in the administrative records of the involved patent and application.

cc:

Anthony M. Zupcic and Robert H. Fischer, Fitzpatrick, Cella, Harper & Scinto, of New York City, New York, for Amgen, Inc.

Richard L. DeLucia and John Kenny, Kenyon & Kenyon LLP, New York City, New York, for Human Genome Sciences, Inc. and Schering Corp.

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(6,844,170),
Senior party.

HEARD: 9 January 2009
DECIDED: 19 February 2009

Before: RICHARD TORCZON, SALLY GARDNER LANE, and MICHAEL P. TIERNEY, *Administrative Patent Judges*.

DECISION – Bd.R. 125 – ON MOTIONS

Opinion for the Board by *Administrative Patent Judge* TORCZON, in which *Administrative Patent Judge* TIERNEY joins. Concurring opinion filed by *Administrative Patent Judge* TIERNEY. Dissenting opinion filed by *Administrative Patent Judge* LANE.

PANEL OPINION

I. Introduction

The junior party (Amgen) filed a motion for judgment against the senior party (HGS) on the theory that the involved HGS claims lack utility. Both parties also moved for additional accorded benefit and for exclusion of exhibits. We GRANT Amgen's motion 1 (utility). We DENY portions of Amgen motion 3 (to exclude evidence) with some observations and caveats, but otherwise DISMISS the remaining motions.

II. Amgen motion 1: lack of utility

A. Issue

Amgen contends that HGS lacks a specific, substantial, and credible utility for its involved claims.[1] HGS contends that its invention may be used directly or indirectly to identify activated T cells differentially, which is said to be a well-established utility.[2] Would a skilled reader have believed that the HGS disclosure established differential identification of activated T cells using the claimed polynucleotide as a specific, substantial, and credible use?

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[1] Paper 33 (Amgen Substantive Mot. 1) at 2. Amgen's motion also urges unpatentability on two additional theories under 35 U.S.C. 112(1). Paper 33 at 17-19. Both § 112(1) theories are variations on its utility theory and will be treated as standing or falling with utility.

[2] Paper 38 (HGS Opp. 1) at 2.

B. Findings

1. Claim 15, a representative claim

Neither party addressed the utility of the individual claims. We treat HGS claim 15 as representing the claims in question,[3] HGS involved claims 1-34.[4] HGS claim 15 also defines count 1, the sole count.[5] Claim 15[6] defines the invention as:

> An isolated polynucleotide consisting of a nucleic acid encoding a fragment of SEQ ID NO:2, wherein said fragment is at least 30 contiguous amino acid residues in length and wherein said fragment can be used to generate or select for an antibody that specifically binds the polypeptide of SEQ ID NO:2.

In its disclosure, HGS defines SEQ ID NO:2 as "the deduced amino acid sequence…of CRCGCL."[7] HGS defines "CRCGCL" as "a novel human polypeptide named Cytokine Receptor Common Gamma Chain Like".[8] (Amgen calls the polypeptide "Thymic Stromal Lymphopoietin Receptor" or TSLPR.)[9] For the purposes of Amgen motion 1, the parties do not contest the meaning of HGS claim 15.

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[3] *In re Van Geuns*, 988 F.2d 1181, 1186 (Fed. Cir. 1993): "Of course, if a party chooses not to argue the claims separately, they would stand or fall together."

[4] Paper 4 (Errata for Declaration) at 1.

[5] Paper 1 (Declaration) at 3: "*Count 1*—An isolated polynucleotide of US 6,844,170 claim 15."

[6] Paper 14 (HGS clean claims) at 3.

[7] Exh. 2002 (P.A. Moore et al., Cytokine Receptor Common Gamma Chain Like, U.S. Appl'n 09/263,626, filed 5 March 1999) at 2:23-24.

[8] *Id.* at 1:10-11.

[9] Exh. 2005 at 1:9-10.

The polynucleotide must be able to encode a fragment of CRCGCL protein, which must aid in the production of antibodies to the CRCGCL protein. Hence, a utility for the protein fragment, or the antibodies produced from it, would imply a utility for the polynucleotide that produces the protein fragment as well.

2. The level of skill in the art

The application that resulted in the involved HGS patent was filed 5 March 1999.[10] The parties agree that, at the relevant time, those skilled in the art had considerable training in biology or microbiology and experience with nucleotide characterization or polypeptide expression.[11] The parties also agree that those skilled in the art knew a good deal about signaling receptor complexes called cytokine receptors, particularly interleukin (IL) receptors.[12] Those in the art knew how to search computer data bases for similar polynucleotide and polypeptide sequences, including those relating to cytokine receptors.[13] The parties agree on very little else. We find these points of agreement sufficient to form a picture of a highly skilled professional well acquainted with the molecular-biology, cell-biology, and bioinformatic literature and techniques routinely used in cytokine research.

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[10] Exh. 1001 (involved HGS patent), coversheet, item (22).
[11] Paper 42 (Amgen Reply) at A2-5, material fact 19, admitted as one possible definition. The definition details academic degrees and years of experience, but these alone are not very helpful indicators since they presuppose that the fact-finder already knows what knowledge and abilities they imply. *Argyropoulos v. Swarup*, 56 USPQ2d 1795, 1807 (BPAI 2000).
[12] Paper 42 at A2-5, admitted facts 20 & 21.
[13] *Id.*, at A2-6, admitted facts 23-25.

3. What the HGS disclosure teaches generally

The "field of invention" portion of the disclosure identifies the following uses: making CRCGCL polypeptides, as well as vectors, host cells, and antibodies; detecting and treating immune system disorders; and screening for agonists and antagonists of CRCGCL activity.[14] The abstract also identifies the first two uses.[15] Differential identification of activated T cells is not listed as a use in either of these marquee portions of the specification.

Amgen identified nearly three hundred medical utilities in the disclosure.[16] These utilities are prophetic (in that the specification does not describe the utilities as having actually been demonstrated) or even speculative (in that the utility is broadly suggested by analogy to other systems). For instance, in a typical disclosure regarding the protein produced using the polynucleotide of the count, HGS states:[17]

> The tissue distribution of [the CRCGCL] gene in cells of the immune system suggests that the protein product of this clone would be useful for treatment, prophylaxis and diagnosis of immune and autoimmune diseases, such as lupus, transplant rejection, allergic reactions, arthritis, asthma, immunodeficiency diseases, leukemia, AIDS. In addition its expression in T-cells suggests a potential role in the treatment, prophylaxis and detection of thymus disorders such as Graves [d]isease, lymphocytic thyroiditis, hyperthyroidism and hypothyroidism. The receptor could also serve as a target for small molecule or

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[14] Exh. 2002 at 1:7-16.
[15] *Id.* at 124:1-8.
[16] Exh. 2053 (Chart of Diseases/Disorders/Deficiencies in the HGS Application).
[17] Exh. 2002 at 8:34-9:6.

> monoclonal antibody, blocking its activity, which could be important in the disease states listed herein.

Other disclosed uses for the polynucleotide include the use of—

> variant polynucleotides for optimizing protein production in different host organisms;[18]
>
> polynucleotide fragments as probes or primers;[19]
>
> polynucleotides in gene therapy;[20]
>
> polynucleotides for identification of individuals;[21]
>
> polynucleotides as hybridization probes for differential identification of tissues or cells;[22]
>
> polynucleotides for gene expression level assays;[23] and
>
> polynucleotides as molecular weight markers.[24]

Amgen has provided expert testimony that one of skill reading the HGS application when it was filed would have thought the listed utilities fell below the substantial, specific, and credible thresholds.[25] The expert, Dr. Steven F. Ziegler, testified that HGS misidentified the nature and activity of CRCGCL.[26] Additionally, Dr. Ziegler explained that one of skill reading

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[18] *Id.* at 14:13-16.
[19] *Id.* at 17:6-29.
[20] *Id.* at 42:21 & 46:4-55:28.
[21] *Id.* at 42:26-43:15.
[22] *Id.* at 8:21-31 & 43:23-27.
[23] *Id.* at 44:1-6.
[24] *Id.* at 44:7-12.
[25] Exh. 2003 (Subst. Decl. of Steven F. Ziegler) at 8-9.
[26] *Ibid.*

the HGS disclosure when filed would have been skeptical about the inferences HGS drew based solely on homology to other sequences.[27]

4. The differential identification disclosure

During examination and in this interference, HGS relied on differential identification of activated T cells as demonstrating the requisite utility.[28] According to HGS, its "patent discloses that the CRCGCL/TSLPR polynucleotide, polypeptide and antibodies thereto can detect activated T-cells."[29]

The HGS specification discloses that SEQ ID NO:2 (the polypeptide sequence used to define the claimed polynucleotides) was deduced from the sequence of a clone isolated from an activated T-cell cDNA library.[30] The nature and source of the activated T cells comprising the library is not disclosed.

An assay for expressed polynucleotides is disclosed as having shown a polynucleotide transcript of the expected size—[31]

> in a cervical cancer cell line (HeLa), activated T-cells, and a lung carcinoma cell line (A549), while a shorter variant is also expressed in the lymph node and to a lesser extent in the spleen tissues, a pattern consistent with immune specific expression.
>
> CRCGCL expression was not observed in the following cell lines, HL60, K562, Molt-4, Raji, SW480, G361, as well as the heart, brain, placenta, lung, liver, skeletal muscle, kidney, pancreas, thymus, prostate, testis, ovary, small intestine, colon,

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[27] *Id.* at, *e.g.*, 11, ¶23; 11-12, ¶26; and 13-14, ¶31.
[28] Paper 38 at 2:7-3:4.
[29] *Id.* at 6:24-26.
[30] Exh. 2002 at 7:3-9.
[31] *Id.* at 7:15-23.

> or peripheral blood leukocytes, a pattern consistent with immune specific expression.

Molt-4 is a T-cell line.[32] The specification proceeds to suggest—[33]

> Because CRCGCL was isolated from activated T cells, nucleic acids of the invention are useful as reagents for differential identification of the tissue(s) or cell type(s) present in a biological sample and for diagnosis of immune disorders.

Similarly, the specification states—[34]

> Because CRCGCL is found expressed in a cervical cancer cell line (HeLa), activated T cells, and a lung carcinoma cell line (A549), while a shorter variant is also expressed in the lymph node and to a lesser extent in the spleen, CRCGCL polynucleotides are useful as hybridization probes for differential identification of the tissue(s) or cell type(s) present in a biological sample.

HGS provides the expert testimony of Dr. Zurawski,[35] who stated that similar disclosure appears in HGS provisional applications associated with the involved HGS application.[36] Dr. Zurawski explained that markers for activated T cells would have been, at the time of filing, considered useful.[37]

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[32] *Id.* at 88:25-27.

[33] *Id.* at 8:21-23. The present-tense wording of this suggestion is confusing. It is not an example, in which present tense is used to indicate the example is prophetic. *Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1376 n.1 (Fed. Cir. 2003). HGS has not, however, indicated that it had actually used CRCGCL polynucleotides (or polypeptides) for differential identification by the time its involved application was filed. We thus find this wording indicates an expectation rather than an established fact.

[34] *Id.* at 43:23-27.

[35] Exh. 1014 (Supp. Zurawski Decl.).

[36] *Id.* at 21, ¶49.

[37] *Id.* at 22-26, ¶¶52-62. Although there is some controversy in the record regarding whether such markers worked, we accept for our decision on this

HGS notes that on cross examination Dr. Ziegler, Amgen's expert, admitted he had not discussed whether the CRCGCL polypeptide (as opposed to the polynucleotide of the count) could be used to detect activated T cells.[38] Dr. Ziegler testified in a subsequent cross examination, however, that he had in fact considered that utility in his declaration testimony and misspoke when he testified that he had not.[39] Dr. Ziegler's declaration testimony regarding differential identification mentions polypeptides, but in the context of a utility for CRCGCL polynucleotides:[40]

> In addition, the assertion that nucleotides for CRCGCL may be useful for "differential identification" of tissue or cells in a biological sample is also the case for virtually any polypeptide, and provides the person of ordinary skill no information regarding a utility specific to CRCGCL.

While this statement may be ambiguous, the reason Dr. Ziegler gives is applicable to both the polynucleotides and the polypeptides. As he notes, indicating a source cell is not in itself a specific utility.

The HGS disclosure itself identifies two assays that screen for activated T cells.[41] These two assays are used to test whether CRCGCL peptide activates T cells.[42] None of the examples in the disclosure, however,

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motion that a working marker for activated T cells was considered to be worth having at least as a research tool.

[38] Paper 38 at 33:10-22, citing Exh. 2058 at 117:2-18.

[39] Exh. 2073 at 191:21-192:4.

[40] Exh. 2003 at 22-23, ¶49.

[41] Exh. 2002 at 88:20-89:36 (Example 14, using a secreted reporter molecule) and 92:21-94:2 (Example 17, using a transcription promoter).

[42] *Id.* at 82:28-30 and 88:21-22.

show CRCGCL polynucleotides or polypeptides used for differential identification of activated T cells.[43]

One of the assays for T-cell activation states that Molt-4 cells could be used in the assay as the T cells to be activated.[44] The example, however, describes using a different T-cell line. The example is worded in the present tense, indicating it is a prophetic example.[45]

Dr. Ziegler testified that the purported utility exceeds what a skilled reader would understand the HGS disclosure to establish. In particular, the disclosure reports that CRCGCL is expressed in two cancer cell lines in addition to its presence in an activated T-cell library.[46] Conversely, CRCGCL is not expressed in other cells, including a T cell, and tissues associated with the immune system. The tissues are said to be rich in activated T cells yet showed no activity.[47]

Dr. Zurawski explains that techniques exist for excluding cells other than T cells, such as also using general markers for T cells or examining cell morphology, which would presumably exclude cells from the two cancer cell lines.[48] He does not indicate where the HGS disclosure discusses these techniques. The indicated techniques appear to be within the skill of the art.

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[43] Exh. 2002 at 68-113, Examples 1-31.
[44] Exh. 2002 at 88:25-27.
[45] *Id.* at 88:20-89:36. The result reported at the end is for a positive control, and thus does not indicate an actual running of the assay.
[46] Exh. 2003 at 20, ¶42.
[47] *Id.* at 21, ¶43. We understand from the record for another motion that the significance of this fact is in dispute.
[48] Exh. 1014 at 26-27, ¶63.

Dr. Zurawski also suggests that a marker for disease-associated cells is itself useful,[49] but this suggestion exceeds what the HGS disclosure actually establishes. At best, the HGS disclosure indicates that CRCGCL expression is associated with some disease-associated cells (activated T cells and some cancer cells), but not other cells (including some other cancer cells).

Similarly, based on the HGS disclosure, CRCGCL would not be useful for distinguishing activated T cells from other cells generally. If tissues likely to harbor activated T cells do not show evidence of CRCGCL, then the sophisticated reader would conclude that either CRCGCL is not effective, it is not very sensitive, or additional study is warranted to understand what is really happening. Similarly, evidence of CRCGCL in two cancer cell lines suggests that CRCGCL is likely to be expressed in cells and tissues other than activated T cells. Thus, the best case for a differential identification utility is limited to distinguishing between activated and unactivated T cells.

5. Post-filing evidence

We give no weight to the prosecution history regarding utility since it was decided on a different record, without the participation of Amgen, and with a different declarant who was not provided for cross examination.[50] To the extent that Dr. Zurawski has adopted the prosecution declarant's testimony as his own, we have considered it as Dr. Zurawski's testimony.

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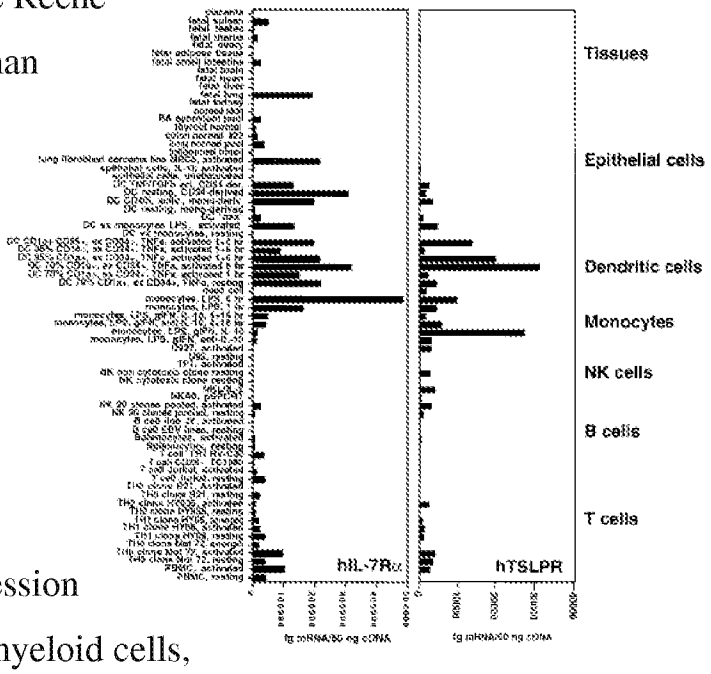
[49] *Id.* at 26-27, ¶63.

[50] *Glaxo Wellcome, Inc. v. Cabilly*, 56 USPQ2d 1983, 1984 (BPAI 2000), *citing Switzer v. Sockman*, 333 F.2d 935, 942 (CCPA 1964) *and Sze v. Bloch*, 458 F.2d 137, 141 (CCPA 1972).

Both parties rely on post hoc publications to support the conclusions of their experts. Two research papers in particular, Reche[51] and Rochman,[52] stand out as particularly pivotal to the positions of the parties.[53]

The Reche paper reports using a TSLP receptor identified from a proprietary HGS database.[54] Reche concludes that the gene is likely to be a human analog to the previously identified murine TSLPR rather than a gamma chain receptor based on greater homology to the murine TSLP receptor.[55] The name of the Reche paper, announcing that human TSLP preferentially stimulates myeloid cells, is telling. Reche Figure 4[56] (right) shows expression profiles for human TSLPR and an interleukin receptor. Significantly, TSLPR expression is far more pronounced in myeloid cells, especially dendritic cells, than it is in lymphoid cells, which include T cells.



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[51] Exh. 2032: Pedro A. Reche et al., *Human Thymic Stromal Lymphopoietin Preferentially Stimulates Myeloid Cells*, 167 J. Immunol. 336 (2001).
[52] Exh. 2033: Irina Rochman et al., *Cutting Edge: Direct Action of Thymic Stromal Lymphopoetin on Activated Human CD4$^+$ Cells*, 178 J. Immunol. 6720 (2007).
[53] Paper 38 at 16-18 and Paper 42 at 5-6.
[54] Exh. 2032 at 338 (left).
[55] *Id.* (right).
[56] *Id.* at 340.

Moreover, among lymphoid cells, expression levels in NK cells are comparable to those in T cells. Among T cells, there appears to be little correlation between expression and status since there are examples of activated, anergic, and resting T cells both expressing and not expressing (albeit when the activated T cells do express TSLPR it is at slightly higher levels than for anergic and resting T cells). These results were published approximately two years after the relevant filing date. Thus, they cannot be imputed to the knowledge of one reading the HGS disclosure at the time it was filed. They do, however, support Dr. Ziegler's testimony regarding the unpredictability of the art at the relevant date, since the Reche results suggest unpredictability even later, and hence the skepticism with which the claims in the HGS specification would have been viewed in the art.

The Rochman paper, which was published about eight years after the relevant date, is directed to the action of TSLP on activated T cells.[57] Rochman starts from the premise that TSLP acts on murine, but not human, T cells and reports that, unexpectedly, TSLP does act on at least some human T cells.[58] Since the paper does not account for the HGS disclosure (which was already available as a patent), Rochman's reports about the knowledge of the art and the unexpectedness of the results is entitled to little weight in the context of this motion. To the extent Rochman characterizes Reche's results as showing no significant activity in T cells,[59] however, it is probative of how those in the art understood Reche's results.

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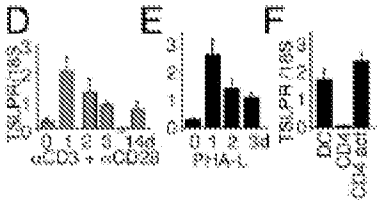
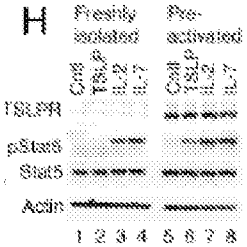
[57] Exhibit 2033, title.
[58] *Id.* at 6720.
[59] *Id.* at 6721 (right), citing endnote 16.

Rochman reports that "freshly isolated" T cells had little TSLPR polynucleotide activity, but activated cells showed polynucleotide activity peaking at one day and then persisting for fourteen days. Panels D-F of Rochman Figure 1 (right) show TSLPR polynucleotide activity in unactivated and activated T cells, while panel F compares polynucleotide activity to dendritic cells as well. The panels show activity for all cells, but higher activity for the activated $CD4^+$ T cells, even compared to dendritic cells. Panel H of Rochman Figure 1 (left) shows a similar assay with antibodies to TSLPR, which shows no discernable TSLPR protein for freshly isolated T cells, but the presence of TSLPR protein for activated T cells.[60] Based on Panel H, which appeared in 2007, skilled readers would have had more persuasive evidence that TSLPR antibodies could be used in a differential assay.





C. Analysis

1. Legal standard

The utility requirement is principally found in § 101 of the Patent Code,[61] which codifies the constitutional mandate that inventors must earn their patents by contributing to "the *Progress* of...*useful* Arts".[62] Utility is a central concept of patentability.[63] While threshold for proving utility has

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[60] Id. at 6721-22.
[61] 35 U.S.C. 101.
[62] U.S. Const., art. I, § 8, cl. 8 (emphasis added).
[63] *Brenner v. Manson*, 383 U.S. 519, 529 (1966).

been characterized as "not high",[64] case law has consistently rejected arguments in favor of nominal utilities.[65] Instead, precedent has construed § 101 to require that an asserted utility be substantial, specific,[66] and credible.[67]

A use is substantial if the "claimed invention has a significant and presently available benefit to the public."[68] A use is specific if the claimed invention provides "a well-defined and particular benefit to the public."[69] A disclosed utility is not credible if the record contains objective evidence that those in the art would have considered the utility to be inherently unbelievable.[70] Utility is judged from the perspective of one skilled in the relevant art when the application was filed.[71] The utility requirement is satisfied when a properly claimed invention meets at least one stated objective.[72]

2. Burden

As the movant, Amgen has the burden of justifying the relief sought.[73] Moreover, a utility in the specification is presumed to be correct.[74]

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[64] *In re Fisher*, 421 F.3d 1365, 1370 (Fed. Cir. 2005) (attributing the characterization to the parties).
[65] *Id.* at 1370-71, *following Manson*, 383 U.S. at 534-35.
[66] *Fisher*, 421 F.3d at 1371, *following Manson*, 383 U.S. at 534-35.
[67] *In re Cortright*, 165 F.3d 1353, 1357 (Fed. Cir. 1999).
[68] *Fisher*, 421 F.3d at 1371 (noting that "practical" and "real-world" are alternate formulations for the "substantial" requirement).
[69] *Fisher*, 421 F.3d at 1371.
[70] *Cortright*, 165 F.3d at 1357.
[71] *In re Swartz*, 232 F.3d 862, 863 (Fed. Cir. 2000); *Cortright*, 165 F.3d at 1357 (noting that what the art considered possible had changed over time).
[72] *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958-59 (Fed. Cir. 1983).
[73] Bd.R. 121(b) (burden on movant).

Demonstrating an absence of utility, however, requires proof of a negative. The threshold for shifting the burden is generally lower in this circumstance.[75] The problem is further compounded by the nature of the HGS specification, which lists an enormous number of potential uses but very little supporting disclosure that is specific to the actual use of CRCGCL polynucleotide or its products. In the present case, Amgen's expert testimony regarding how a skilled reader would understand the disclosure was sufficient to shift the burden of production to HGS to identify a specific use. Only then could the issue be properly joined. HGS relies on differential identification of activated T cells to meet this burden. The ultimate burden of proof for lack of utility remains with Amgen.

3. Note on post hoc evidence

The Board cannot rely on post hoc evidence as affirmatively establishing a prior appreciation.[76] Our principal review court has explained that regarding post hoc testing as consistent with the purported appreciation is inappropriate, irrelevant, and unhelpful. The negative use of post hoc evidence, on the other hand, is supported in precedent.[77] Both parties have relied on post hoc evidence on the question of what skilled readers would have understood when the HGS application was filed. We emphatically do

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[74] *Swartz*, 232 F.3d at 864.
[75] *Ibid.* (shifting burden on showing of reasonable doubt); *Biotec Biologische Naturverpackungen v. Biocorp., Inc.*, 249 F.3d 1341, 1354 (Fed. Cir. 2001) (allowing burden shift based on movant's expert testimony).
[76] *Henkel Corp. v. Proctor & Gamble Co.*, _ F.3d _ n.2, 2009 WL 691295 (Fed. Cir. 2009)
[77] *E.g., Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1376 (Fed. Cir. 1999) (holding post hoc failure probative, but post hoc success by others not probative).

not consider this evidence in evaluating the state of mind of the inventors or the hypothetical skilled reader; rather, we consider it only for its value in evaluating how significant, presently available, well-defined, and particularly beneficial the purported utility proved to be. Contrary results using common materials or techniques and publication in a refereed journal are both admissible indicators that earlier disclosure should be viewed with caution.[78]

4. Substantial

The purported utility of differentially identifying activated T cells was neither significant nor presently available when HGS filed its application. In so holding, we assume that a skilled reader would have been able to discern this use from the welter of false leads in the specification.

The purported use would not have been regarded as significant because the data and guidance supporting the use was too limited to be convincing given the unpredictability in the art. The precise utility suggested now—distinguishing between activated and resting T cells—is not expressly disclosed. Rather, the specification only says CRCGCL polynucleotides may be a marker to distinguish cells and tissues in which it is expressed from those in which it is not expressed.[79] This utility is a biotechnological tautology unless CRCGCL is somehow particularly useful for this purpose. After all, the disclosure that CRCGCL had "a pattern consistent with immune specific expression" suggests that there were polynucleotides used earlier to establish that pattern and that would thus also

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[78] *Id.*
[79] Exh. 2002 at 8:21-23.

be markers for such tissues and cells.[80] The utility now being contested is not so broad, however.

The evidence for the narrower utility—distinguishing activated and unactivated T cells—as significant and presently available is not persuasive. At best, the specification indicates differential expression between a proprietary activated T cell and an immortalized resting T cell (Molt-4). While we are not persuaded that Molt-4 is "activated" in a relevant sense despite Dr. Ziegler's testimony, we are also not persuaded that Molt-4 is representative of normal resting T cells either. Those in the art would have known that in general results can vary between cell lines, as the later Reche article illustrates for this subject matter. The narrowest disclosed utility—distinguishing between a proprietary T-cell line and Molt-4—would not have been viewed as significant. Rather, the disclosure provides precisely the sort of suggestion for further research that the Supreme Court has cautioned against. Certainly, the disclosure would not have been enough to make differential T-cell identification presently available, not even as a research tool. The HGS reply indicates as much when it discusses additional markers or analyses that might be necessary.

5. Specific

The purported utility of differentially identifying activated T cells was neither well-defined nor particularly beneficial when HGS filed its application. As noted above, the broad disclosed utility of distinguishing between cells and tissues that express CRCGCL polynucleotide or protein and those that do not is simply a function of any expressed gene. If this

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[80] *Id.* at 7:15-23.

were a well-established and particularly beneficial utility then any isolated gene, regardless of biological function, has a specific utility as a research tool. The narrower utility of T-cell differentiation is even less supported. Given the significant unpredictability in the cell, two data points (one of them an immortalized cell) would not have established a utility for all T cells even in a laboratory environment. There does not appear to be any particular benefit to distinguishing between the HGS proprietary T-cell line and Molt-4.

Dr. Zurawski's testimony regarding the clinical value of the contested utility suggests an excessively broad understanding of what constitutes a specific utility. His analogy to a thermometer is telling. While a thermometer is a relatively limited diagnostic instrument, it is well-adapted to determining whether a temperature is normal or not (i.e., higher or lower than the normal range). The connection between the thermometer reading and the diagnostic information is simple and direct. By contrast, based on what HGS disclosed, detection of CRCGCL expression alone does not exclude the possibility of non-disease related expression in other cells and would plainly miss some T-cell related disease conditions. There simply is not enough information in the disclosure for a skilled reader to draw any firm conclusions about how the invention would work in practice. Consequently, the contested utility cannot be considered well established.

6. Credible

The case law appears to reserve the credibility prong for utilities that are facially unbelievable. If this is the entire scope of the test, then the contested utility passes. Since distinguishing between cells that do and do

not express a protein would be an inherent function of any such protein and its gene, those in the art would have little problem believing the invention might work for that purpose.

Those skilled in the relevant art would not have believed the utility HGS now contests, but not because it is inherently incredible. Rather, they would have considered the possibility so poorly established that much further research would have been necessary. This sort of credibility problem, however, is handled under the specific-utility factor.

7. Effect of other objectives

In its opposition, HGS argues that "statements of additional utilities cannot denigrate a credible utility",[81] citing *Raytheon Co.*[82] and *In re Gottlieb.*[83] In *Raytheon Co.*, the court reversed a lower court for misapplying the Supreme Court's *Mitchell* precedent.[84] In *Mitchell*, the court deemed the invention as taught and claimed to be too dangerous to use.[85] By contrast, in *Raytheon Co.*, the court held that some of the claims accomplished at least one of the specified objectives, even though the disclosed theory of operation was not correct.[86] Similarly, *Gottlieb* distinguishes *In re Novak*,[87] on the question of an apparently inoperative utility in humans. In *Novak*, only a human utility was at issue, while in

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[81] Paper 38 at 5:24-28.
[82] 724 F.2d at 958.
[83] 328 F.2d 1016, 1019 (1964).
[84] *Mitchell v. Tilghman*, 86 U.S. (19 Wall.) 287, 396-97 (1873).
[85] *Ibid.*
[86] 724 F.2d at 959.
[87] 306 F.2d 924, 928 (CCPA 1962).

Gottlieb, the court held that a separate utility in plants was adequate to overcome the rejection.

None of these cases hold that additional utilities are irrelevant; rather, they cumulatively support the unremarkable proposition that utility determinations, including the interplay between claimed inventions and disclosures, are highly fact-dependent. None of these cases touch on the relevant interplay here, which involves a long list of speculative uses with little actual support. In the present case, the thin, scattershot nature of the disclosure would have adversely affected the credence a skilled reader would have given to any of the teachings. This factor is far from dispositive in itself, but is certainly relevant to Amgen's contentions regarding how those of skill in the art would have regarded the disclosure.

D. Conclusion

At face value, the putative utility of providing a marker for activated T cells failed to provide progress to the useful arts. At best, it only teaches that a factor isolated from a source can be a marker for the source. This self-evident teaching is neither substantial nor specific enough to satisfy the utility requirement of § 101. Amgen motion 1 for judgment of unpatentability against all of the involved HGS claims is GRANTED.

III. Amgen motion 3: to exclude evidence

Amgen's motion can be divided into two broad categories. First, Amgen objects to Dr. Zurawski's testimony. Second, Amgen objects to the way that HGS uses much of the post-hoc evidence. The motion is GRANTED in part.

A. Exhibit 1014 - first Zurawski declaration

Most of Amgen's objections are better handled on the merits and we have done so above. To the extent that Dr. Zurawski's testimony was irrelevant or insufficiently supported, we have decreased the weight we have given the testimony. In particular, we have noted Dr. Zurawski's reliance on Dr. Migone's declaration, but have only considered it to the extent that Dr. Zurawski has adopted the testimony as his own. We note that the bases of an expert's testimony need not be admissible on their own.[88] We agree, however, that an examiner's decision in an ex parte examination on a different record is not the sort of basis that is entitled to much weight.[89] We DENY the motion with regard to Exhibit 1014 (as supplemented and filed).

B. Post-hoc journal articles

The principal objection to most of the post-hoc documentary evidence is that it is hearsay. The journal articles meet the definition for hearsay to the extent they are being offered for the truth of what they assert[90] and are properly excluded for that purpose. They are, however, not hearsay as evidence of what the relevant scientific literature was reporting and indeed represent the very "art" we must consider.[91] Thus, for the journal articles

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[88] *Monsanto Co. v. David*, 516 F.3d 1009, 1016 n.4 & text (Fed. Cir. 2008).
[89] *Okada v. Hitotsumachi*, 16 USPQ2d 1789, 1790-91 (Comm'r 1990).
[90] Fed. R. Evid. 801(c).
[91] ADVISORY COMMITTEE NOTES to Rule 801(c) (1972 Proposed Rules): "If the significance of an offered statement lies solely in the fact that it was made, no issue is raised as to the truth of anything asserted, [then] the statement is not hearsay.... The effect is to exclude from hearsay the entire category of 'verbal acts' and 'verbal parts of an act' in which the statement itself affects the legal rights of the parties or is a circumstance bearing on conduct affecting their rights."

pertinent to Amgen motion 1 (including the opposition and reply), the motion is DENIED with respect to the journal articles, but the use of the exhibits is limited to showing what the art thought as of the respective publication dates.

C. Exhibits supporting other motions

The motion is DISMISSED with respect to the exhibits used exclusively in the briefing of motions other than Amgen motion 1 (including HGS opposition 1 and Amgen reply 1).

CONCURRING OPINION

TIERNEY, *Administrative Patent Judge*, concurring.

While the panel opinion adequately addresses the facts of this case, I write separately to highlight the corrosive nature of the practices this case exposes.

Utility presents a question of fact. *Cross v. Iizuka*, 753 F.2d 1040, 1044 (Fed. Cir. 1995). Fact questions are particularly ill-suited to per se treatment. Thus, defining the threshold for utility as "not high" for all cases is inappropriate. A relevant fact in every utility case is the predictability of the art. Speculation in an unpredictable art is not likely to support a substantial, specific, and credible utility.

One need only read Human Genome Sciences' specification to appreciate that the drafter was just guessing about possible utilities. The guesses were educated guesses in the sense that they drew on general knowledge in this field. The scope of the speculation, however, is on its face ludicrous. Treating AIDS? anthrax? yersinia (plague)? HGS does not even bother to defend these uses now that it is pressed. Instead, it relies on differential identification of cells and tissues, but what cells and tissues? We are left to speculate.

The specification makes clear that CRCGCL was isolated from an activated T-cell line so one may reasonably guess that activated T cells are being differentially identified, but against what other tissues or cells? HGS never says in the specification. The specification says that CRCGCL is not detected in some cells and tissues but, as the panel opinion explains, no firm conclusion could be reasonably based on even this indirect suggestion.

Those in the art would not stand for such a disclosure. The patent system does not have to stand for it either.

This case illustrates the Supreme Court's concerns about a patentee dominating an important technology without contributing to progress in that technology. In *Brenner v. Manson*, 383 U.S. 519, 530-31 (1966), the Court rejected the notion that a nominal utility—yielding the intended product—was enough to make a process useful. It also rejected the notions that potential utility warranting serious scientific research and that the product's homology to other useful compounds were sufficient utilities. 383 U.S. at 536. As the Court famously noted, "a patent is not a hunting license." 383 U.S. at 536. Indeed the Court expressed concern that patenting on the basis of a nominal utility would create disincentives to invest in the research necessary to find practical, readily useful applications.

It is important to remember that the process involved in *Manson* was in fact useful. Manson, after all, wanted an interference with a patent issued to Ringold and Rosenkranz. 383 U.S. at 520-21. Manson's problem was that Ringold and Rosenkranz knew what they had and had disclosed a utility for it, while Manson had not. Similarly, HGS cannot be rewarded for educated speculation based on homology and some very preliminary results. HGS did not demonstrate in its specification any practical utility capable of immediate real-world application. The large number of possible utilities in the specification made the amount of experimentation necessary to determine which might be useful so onerous that it was an unreasonable, even if much of it would have been routine.

The dissent's discussion of *In re Cortright*, 165 F.3d 1353 (Fed. Cir. 1999), does not help. Cortright at least provided examples showing the

baldness treatment working. Moreover, Cortright did not hide that utility in a large number of speculative alternative uses. HGS, by contrast, provides no such examples, no specific comparisons, and no guidance as to which of the myriad possibilities it discloses is the real utility.

Utility must be apparent from the specification itself at the time of filing. No person, however skilled in this art, would have been able to discern at the time of filing that distinguishing activated and inactivated T cells was the substantial, specific, and credible utility that HGS intended to contribute to the progress of the useful arts among all of the other faint and false trails disclosed.

The integrity of the patent system as a tool for promoting progress in the useful arts requires a finding of no utility on the facts of this case.

DISSENTING OPINION

LANE, *Administrative Patent Judge*, dissenting.

Human Genome Sciences (HGS) disclosed that polynucleotides encoding CRCGCL can be used directly or indirectly to identify activated T cells. HGS also discloses two examples (Examples 14 and 17) in which a handier way of identifying activated T cells would have been useful. Given the high level of skill in this art, this suggestion is enough to satisfy the utility requirement of 35 U.S.C. § 101.

Ideally, HGS would have drafted a better focused specification. Few disclosures are ideal, however. We must decide the case on the record we have.

Precedent makes clear that the threshold for utility is low. In this regard, *In re Cortright*, 165 F.3d 1353 (Fed. Cir. 1999), is instructive. Cortright claimed the use of a cow udder ointment (BAG BALM®) in a method for treating human baldness. The examiner required Cortright to provide evidence in support of the utility, which the examiner considered incredible, and discounted the disclosed and claimed mechanism of treatment as "only speculation." When no evidence was provided, the examiner rejected the claims as lacking utility under 35 U.S.C. § 101. On appeal, the Board reversed the utility rejection on the basis of Cortright's disclosed examples, but substituted a related rejection under 35 U.S.C. §112, first paragraph, for lack of disclosure that would enable the effective use of BAG BALM® as claimed. 165 F.3d at 1355. On judicial review, the Court of Appeals for the Federal Circuit reversed even the substituted ground. The court noted that the Office had issued other patents for baldness treatments, so a baldness treatment could not be inherently incredible. 165 F.3d at 1357.

Moreover, the court concluded from the disclosure and claims that any hair growth at all would be sufficient. Since one example gave a dosage and a duration for the treatment, the court concluded that the claimed baldness treatment was amply supported and reversed the rejection for the broadest claim. 165 F.3d at 1359. The court affirmed the rejection of a claim limited to a specific mechanism for treatment. 165 F.3d at 1360.

The differential identification at issue here is as credible as Cortright's use of BAG BALM® as a baldness treatment. Although HGS does not give a specific example of CRCGCL being used to differentially identify activated T cells in a heterogeneous tissue or cell sample, the level of skill in this art is so high that, if the method works at all, those in the art could quickly determine that fact. No one provided test results that indicate whether differential identification performed using CRCGCL as described in the HGS specification would or would not work. Thus, we are left with the presumption that the claimed invention does what it is described to do.

The qualms of the majority are understandable. Any naturally occurring polynucleotide or polypeptide, or any antibody to the polypeptide, can be used as a marker, even if additional markers are necessary for effective identification. Thus, all naturally occurring polynucleotides or polypeptides are prima facie useful the minute they are isolated from a known source. For better or worse, precedent requires a finding of utility in this circumstance.

cc:

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